K121436

Attachment 5

JUN 06 2013

DAS Medical, LLC
Columbus, MS 39701

510k Summary

510k Summary for: DAS Medical Equipment Drapes

Date Prepared: December 18, 2012

Firm: **DAS Medical, LLC**
100 Rosecrest Lane
Columbus, MS 39701
662-497-2866

510k submitter and Contact: Armond Groves – Managing Partner

Owner/OperatorNumber: 10036300

Device Common Name: Equipment drapes

Device Trade Name: DAS Medical Equipment drapes

Classification Name: Surgical Drapes and Drape Accessory

Regulation number: 878.4370

Classification: II

Panel: General and Plastic Surgery

Product code: KKX

Description of device:
The DAS Medical, LLC equipment drapes are used to cover a variety of equipment in the surgical setting, as well as other clinical areas where protection is necessary to prevent contamination of medical equipment from fluids or other contaminants. Equipment drapes are supplied non-sterile and sterile. The non-sterile version is supplied primarily for re-packers and re-labelers. Sterile, disposable, single use applications are supplied to a distributor or directly to the end-user. These devices are specifically designed for a variety of surgical and general hospital equipment, such as microscopes, cameras, monitors, tables, robotics, c-arms and various other x-ray and/or similar equipment. The DAS Medical Equipment Drapes are manufactured with polyethylene cut to form to a specific shape for the equipment they are intended to cover. Adhesive tape, bands, elastic, and hook and loop attachments are applied to the products in specific areas to aid in positioning and securing the product to the equipment. All of these devices are non-patient contacting. These equipment drapes are substantially equivalent to other drapes currently being marketed for the same purpose.

DAS Medical, LLC
Columbus, MS 39701

Intended Use/Indications for Use:
The DAS Medical, LLC equipment drapes are used to cover a variety of equipment in the surgical and clinical areas where protection is necessary to prevent contamination of medical equipment from fluids or other contaminants in the clinical setting. Equipment drapes are non-patient contact.

Substantial Equivalency Comparison Chart

Company	DAS Medical, LLC	Medline K032065	Volcano Corporation K052395
Design	Equipment Drape – Various designs and sizes	**Similarities:** Equivalent intended use **Differences:** Sizes and added options may vary slightly by manufacturer – marketing options.	**Similarities:** Equivalent intended use **Differences:** Sizes and added options may vary slightly by manufacturer – marketing options.
Functionality	The DAS Medical, LLC equipment drapes are used to cover a variety of equipment in the surgical setting, as well as other clinical areas where protection is necessary to prevent contamination of medical equipment from fluids or other contaminants in the clinical setting. Single use device: Non-patient contacting.	**Similarities:** Equivalent **Differences:** None	**Similarities:** Equivalent **Differences:** None
Intended Use/Indications for Use	The DAS Medical, LLC equipment drapes are used to cover a variety of equipment in the surgical and clinical areas where protection is necessary to prevent contamination of medical equipment from fluids or other contaminants in the clinical setting. Equipment drapes are non-patient contact.	**Similarities:** Equivalent **Differences:** None	**Similarities:** Equivalent **Differences:** None
Sterile/NS	Sterile and Non-sterile	**Similarities:** Equivalent **Differences:** None	**Similarities:** Equivalent **Differences:** None

Sterilization	EO/Gamma	**Similarities:** Equivalent **Differences:** None	**Similarities:** Equivalent **Differences:** None
Material	Polyethylene	**Similarities:** Equivalent **Differences:** Raw material manufacturer/ proprietary blend and weight	**Similarities:** Equivalent **Differences:** Raw material manufacturer/ proprietary blend and weight
Flammability	Class I	Equivalent	Equivalent
Technological Characteristics	Polyethylene drapes manufactured to cover a variety of equipment to protect from contamination	**Similarities:** Equivalent **Differences:** Drapes may vary by additional added features	**Similarities:** Equivalent **Differences:** Drapes may vary by additional added features
Physical Testing	Tensile-ASTM D882 Water Resistance/Impact Penetration-AATCC 42/INDA IST Method 80.3 Flammability-16 CFR, Part 10- Class I Tear Resistance-ASTM D1004	**Similarities:** Equivalent **Differences:** None	**Similarities:** Equivalent **Differences:** None
Labeling	Sterile/Non-sterile, Single Use, Disposable	**Similarities:** Equivalent **Differences:** None	**Similarities:** Equivalent **Differences:** None
Instructions for Use	No instructions for use provided. These drapes have generally known usages and instructions.	**Similarities:** Equivalent **Differences:** None	**Similarities:** Equivalent **Differences:** None
Performance Data	No additional performance data is necessary.	**Similarities:** Equivalent **Differences:** None	**Similarities:** Equivalent **Differences:** None

Summary

A comparison of all non-clinical testing data from pre-determined characteristics of these products and materials used in the manufacture of these products was performed. DAS Medical, LLC has determined these products have met the acceptance criteria for

performance testing including impact penetration, tear strength, tensile strength, and flammability and meet the pre-determined characteristics of the material properties for functionality, safety, and effectiveness for the intended use of the products. DAS Medical, LLC has determined these products are substantially equivalent to the predicate devices stated in this submission.

Conclusion

All information supplied in this Premarket Notification support the determination that this device is substantially equivalent to the predicate devices listed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

June 6, 2013

DAS Medical, LLC
C/O Mr. Armond Groves
100 Rosecrest Lane
COLUMBUS MS 39701

Re: K121436
Trade/Device Name: DAS Medical Equipment Drapes
Regulation Number: 21 CFR 878.4370
Regulation Name: Equipment Drapes
Regulatory Class: Class II
Product Code: KKX
Dated: May 31, 2013
Received: June 5, 2013

Dear Mr. Groves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number – K121436

Device Name: DAS Medical Equipment Drapes

Indications for Use Statement:

The DAS Medical, LLC equipment drapes are used to cover a variety of equipment in the surgical and clinical areas where protection is necessary to prevent contamination of medical equipment from fluids or other contaminants in the clinical setting. Equipment drapes are non-patient contact.

Equipment Drapes	Descriptions	Model #
Microscope Drapes	48" X 120" (122 X 305 cm) with tape	MD48120T
	48" X 120" (122 X 305 cm) with hook and loop	MD48120H
	52" X 150" (132 X 381 cm) with tape	MD52150T
	52" X 150" (132 X 381 cm) with hook and loop	MD52150H
	20" X 64" (51 X 163 cm) with tape	MD2064T
	20" X 64" (51 X 163 cm) with hook and loop	MD2064H
	41" X 64" (104 X 163 cm) with tape	MD4164T
	41" X 64" (104 X 163 cm) with hook and loop	MD2164H
	41" X 80" (104 X 203 cm) with tape	MD4180T
	41" X 80" (104 X 203 cm with hook and loop	MD4180H
	41" X 105" (104 X 267 cm) with tape	MD41105T
	41" X 105" (104 X 267 cm with hook and loop	MD41105H
	41" X 120" (104 X 305 cm) with tape	MD41120T
	41" X 120" (104 X 305 cm) with hook and loop	MD41120H
	48" X 120" (122 X 305 cm) with tape	MD48120T
	48" X 120" (122 X 305 cm) with hook and loop	MD48120H
	52" X 150" (132 X 381 cm) with tape	MD52150T
	52" X 150" (132 X 381 cm) with hook and loop	MD52150H
	20" X 64" (51 X 163 cm) with tape	MD2064T
	20" X 64" (51 X 163 cm) with hook and loop	MD2064H
	46" X 64" (117 X 163 cm) with tape	MD4664T
	46" X 64" (117 X 163 cm) with hook and loop	MD4664H
	46" X 80" (117 X 203 cm) with tape	MD4680T
	46" X 80" (117 X 203 cm) with hook and loop	MD4680H
	46" X 105" (117 X 267 cm) with tape	MD46105T
	46" X 105" (117 X 267 cm) with hook and loop	MD46105H
	46" X 120" (117 X 305 cm) with tape	MD46120T
	46" X 120" (117 X 305 cm) with hook and loop	MD46120H
	54" X 105" (137 X 267 cm) with tape	MD54105T
	54" X 105" (137 X 267 cm) with hook and loop	MD54105H

Remote Control Cover	4" X 11" (10 X 28 cm)		RC411
	7" X 14" (18 X 35 cm)		RC714
Keyboard Cover	30" X 24" (76 X 61 cm)		KC3024
Footswitch Cover	14" X 30" (36 X 76 cm)		FC1430
Banded Bags	20" X 10" (50 X 25 cm)	20" circular, sewn elastic	BB2010
	30" X 15" (76 X 38 cm)	30" circular, sewn elastic	BB3015
	40" X 20" (102 X 51 cm)	40" circular, sewn elastic	BB4020
	50" X 25" (127 X 64 cm)	50" circular, sewn elastic	BB5025
	60" X 30" (152 X 76 cm)	60" circular, sewn elastic	BB6030
	15" X 15" (38 X 38 cm)	Rectangular, with tape	BB1515T
	30" X 30" (76 X 76 cm)	Rectangular, with tape	BB3030T
	36" X 30" (91 X 76 cm)	Rectangular, with tape	BB3630T
	36" X 54" (91 X 137 cm)	Rectangular, with tape	BB3654T
	40" X 40" (102 X 102 cm)	Rectangular, with tape	BB4040T
Camera Drapes	7" X 96" (18 X 244 cm) with tape		CD796T
	7" X 96" (18 X 244 cm) with hook and loop		CD796H
	54" X 150" (137 X 381 cm) with tape		CD54150T
	54" X 150" (137 X 381 cm) with hook and loop		CD54150H
	5" X 96"(13 X 244 cm) with tape		CD596T
	5" X 96"(13 X 244 cm) with hook and loop		CD596H
	9" X 96" (23 X 244 cm) with tape		CD996T
	9" X 96" (23 X 244 cm) with hook and loop		CD996H
	15" X 64" (38 X 163 cm) with tape		CD1564T
	15" X 64" (38 X 163 cm) with hook and loop		CD1564H
Robotic Arm Drapes	7" X 96" (18 X 244 cm) with tape		RD796T
	7" X 96" (18 X 244 cm) with hook and loop		RD796H
	5" X 96"(13 X 244 cm) with tape		RD596T
	5" X 96"(13 X 244 cm) with hook and loop		RD596H
	9" X 96" (23 X 244 cm) with tape		RD996T
	9" X 96" (23 X 244 cm) with hook and loop		RD996H
	15" X 64" (38 X 163 cm) with tape		RD1564T
	15" X 64" (38 X 163 cm) with hook and loop		RD1564H

All drapes supplied Non-sterile will contain a "NS" after the model number

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.06.06 15:25:55 -04'00'

(Division Sign-Off)
Division of General and Plastic
Surgery Devices

510(k) Number K121436

Prescription Use _____ or Over-The-Counter Use ___X___
(per 21CFR 801.109)